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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/731,868	12/09/2003	Ruchika Singhal	1023-330USD1	6697
28863 7590 03/31/2009 SHUMAKER & SIEFFERT, P. A. 1625 RADIO DRIVE SUITE 300 WOODBURY, MN 55125				
EXAMINER MATTHEWS, WILLIAM H				
ART UNIT 3774		PAPER NUMBER		
NOTIFICATION DATE 03/31/2009		DELIVERY MODE ELECTRONIC		

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

pairedocketing@ssiplay.com

### Office Action Summary

**Application No.**

10/731,868

**Applicant(s)**

SINGHAL ET AL.

**Examiner**

William H. Matthews (Howie)

**Art Unit**

3774

**Period for Reply** -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 12-18-08.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-7, 9-17 and 24-32 is/are pending in the application.
- 4a) Of the above claim(s) 13 and 14 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-7, 9-12, 15-17, 24-32 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/S508)  
Paper No(s)/Mail Date \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_

## **DETAILED ACTION**

### ***Response to Arguments***

Applicant's arguments with respect to claims 1-7,9-12,15-17,24-32 have been considered but are not persuasive.

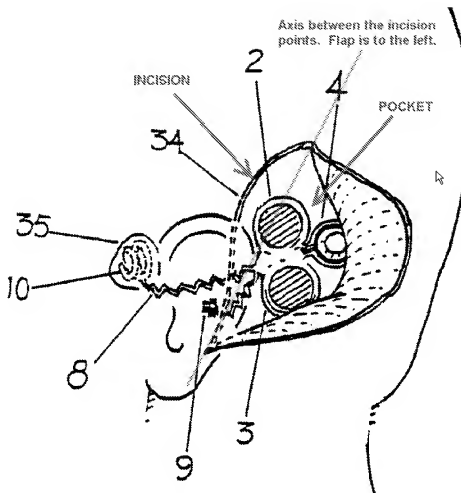
Regarding the 112 1<sup>st</sup> paragraph rejection of claims 12 and 27, Applicant argues the specification provides support for and enables a combination of using a pocket and a recess at paragraphs 0046-0051. Examiner is not persuaded. The "extra stage" referenced in paragraph 46 is the "dummy IMD". Paragraph 51 only describes that a recess may be created to receive an IMD or portion thereof. It fails to describe the recess in connection with a pocket, and especially fails to describe forming a pocket (which is defined as a space behind a fold and incision formed by a spatula, see para 0022), forming a recess, inserting the a portion of the device into the pocket (claim 1,26), and inserting the device into the recess (claim 12,27). Applicant states it would be apparent to one of ordinary skill to form a recess in the pocket. This is not understood because one of ordinary skill in the art would expect a recess to be formed in an exposed region of the skull (i.e. outside of the claimed pocket). Furthermore, since Applicant describes a spatula is used to create the pocket, it is unclear how a tool would be utilized to form a recess therein. To receive such a tool it would seem the pocket must be separated from the scalp to provide space (such as shown in Berrang '914 figure 3) to provide room for a recess forming tool, but Applicant has argued throughout prosecution history that Berrang doesn't teach a pocket, rather a large flap. Regardless, the specification is silent to this issue and thus fails to enable or show that

Applicant possessed the newly claimed invention combining placement of the device in a recess and pocket.

Regarding the 103 rejection, Applicant argues the implantation steps and teachings of Berang and Berang Application would not be obvious.

With respect to claims 1 and 28, Applicant argues the wires in Fischell are "tunneled under the scalp", but figure 15 shows additional wires 616,611 passing through burr hole H1 which is not tunneled. Additionally, Applicant argues Berang and Berang Application are directed to cochlear implants and not directed to leads placed in the brain (i.e. non-analogous art). This is not persuasive because each of the combined references deal with placing implants between the scalp and skull, and are therefore analogous art.

With respect to claims 1, 26, and 28, Applicant argues Berrang and Berrang Application fail to show or suggest a pocket as claimed. Examiner disagrees and provides Figure 3 of Berrang below with notations showing how the figure is interpreted.



The S-shaped incision 34 is shown. The flap would exist to the left of the axis between the start and end points of the S-incision. Inherently, this flap is connected at a fold (the incision S-line). The pocket is to the right of the axis (i.e. behind the incision and flap). Applicant acknowledges that a flap is present in each Berrang invention (Remarks, paragraph 4 of page 4 and paragraph 1 of page 5). Thus if a flap is present, a fold is present along the incision line. This flap is then pulled back to reach the state shown above. Thus it is improper of Applicant to consider the fold shown in figure 3 to the right of, or behind, the implant as the only fold in Berrang. Clearly there is a separation as the implant above occupies the separation.

With respect to claim 12, Applicant states the cited references fail to teach forming a recess in connection with the steps of claim 1. The step of forming a skull recess and placing the device therein is disclosed in Fischell. Fischell is silent as to how the scalp is handled and has been combined with the teachings of Berrang and Berrang Application which teach a method of manipulating the scalp.

With respect to claims 25, Fischell discloses placement of the entire device in a location. Thus if the teachings of the scalp manipulation steps of Berrang or Berrang Application are utilized with the method, it is unclear why Applicant thinks less than all of the device would be placed therein.

With respect to claims 26-27, Applicant is arguing features not claimed.

### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 12 and 27 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Claims 12 and 27 each recite creating a recess and placing the device in the recess **in combination** with placing the device in a

pocket (see claims 1 and 26). Paragraph 51 only describe an alternative placement method for the device and fails to suggest or explain how a recess could be used in conjunction with the pocket.

Claims 12 and 27 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. The combination of placing the device in a pocket **and** placing the device in a recess is not explained in the specification. Furthermore it would not have been readily apparent how a recess could be formed in the pocket (as defined in the specification) such that the device is implanted in both the pocket and recess.

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-7,9-12,15-17,24-32 rejected under 35 U.S.C. 103(a) as being unpatentable over Fischell et al. USPN 6427086 in view of Berrang et al. USPN 6648914 ("Berrang '914") and Berrang US PUB 2003/0109903 (Berrang '903").

Fischell et al. disclose implanting a low profile medical device between a scalp and cranium at the top of the head (see Figure 23). The device may comprise a neurostimulator with brain leads, may be secured via bone screws, and may be implanted in a recess (see abstract and column 31 lines 60- column 32 line 52). Fischell et al. lacks the express disclosure of the implantation steps (claims 1,11,25-29,31), or the specific dimensions of the device recited in claims 2-6.

Berrang '914 teach implantable devices for placement between the scalp and cranium wherein the device includes a control module divided into two modules covered by a flexible overmold (claim 2), thickness of about 4-8mm (claim 3), and a peripheral edge angle of about 135 degrees (claims 5-6) in order to provide the device with cranium conformable features. The implantation steps include administering local anesthetic (claim 17), making a C-shape incision (claim 31), and creating a pocket behind the incision (figure 3) to place the device in the pocket.

Berrang '903 teach implantable devices for placement between the scalp and cranium wherein the device includes a periphery angle of about 135 degrees and wherein the thickness is about 6 mm, and where a flap/pocket method is used (see figure 1-3 and paragraph 46).

Regarding claim 11, the step of suturing a flap would have been readily apparent to close to the flap incisions taught by each of Berrang '814 and Berrang '903.

It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the device and method of implantation disclosed in Fischell et al. to include the features and steps of Berrang '914 and Berrang '913 in order to provide a



low profile, conformable implantation procedure. Furthermore it is well within the level of one of ordinary skill in the art to apply surgical steps known in the art.

### ***Conclusion***

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to William H. Matthews (Howie) whose telephone number is 571-272-4753. The examiner can normally be reached on Monday-Friday 10-6:30PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, David J. Isabella can be reached on 571-272-4749. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/William H. Matthews/  
Primary Examiner  
Art Unit 3774